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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/679,725	10/04/2000	Robert g. Whirley	24641-1070	7345

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RATNER PRESTIA
P.O. BOX 980
VALLEY FORGE, PA 19482

EXAMINER	
PROCTOR, JASON SCOTT	
ART UNIT	**PAPER NUMBER**
2123	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/679,725	WHIRLEY ET AL.	
	Examiner	Art Unit	
	Jason Proctor	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-123* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 were rejected in the Office Action of 11 July 2006.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 November 2006 has been entered.

Applicants' response of 15 November 2006 has amended claims 1, 16, 31, 54, 70, and 86. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 are pending in this application. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-123 are rejected.

Response to Previous Rejections – 35 USC § 102

In response to the previous rejections of claims 1-3, 9, 16-18, 24, 31, 32, 36, 54, 56, 62, 70, 72, 78, 86, 91, 113, 115, 117, 118, and 119 under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,594,651 to St. Ville, Applicants argue primarily that:

> As explained in during the interview, St. Ville does not teach or suggest generating a finite element model or mesh representing both a geometric model of an anatomical feature and a geometric model of a medical device. Instead, St. Ville only teaches generating a finite element model of the object to be manufactured.

The Examiner respectfully traverses this argument as follows.

St. Ville discloses:

> First, a finite element model of the normal bone geometry (both cortical and cancellous layers) is created. (column 16, lines 44-45)
>
> A **finite element model** is again created, but now includes another layer, namely, **the artificial hip embedded in the cancellous bone area.** (column 17, lines 4-6, emphasis added)

Therefore St. Ville plainly discloses generating a finite element model representing both a geometric model of an anatomical feature (normal bone geometry, both cortical and cortical and cancellous layers) and a geometric model of a medical device (artificial hip embedded in the cancellous bone area).

Applicants further argue that:

> Applicants respectfully submit that St. Ville, when read in its entirety, does not disclose the generation of a finite element model representing both a geometric model of an anatomical feature and a geometric model of a medical device. Continuing from the cited lines 4-6, St.Ville column 17 proceed to explain [...] Examining this passage of St. Ville in its entirety, it is clear that the finite element model referenced at column 17, line 4, is the fine mesh model illustrated in Fig. 6 which is made up of a plurality of nodes and elements.

The Examiner respectfully traverses this argument as follows.

St. Ville, when read in its entirety, discloses at least **a finite element model** [that includes] **the artificial hip embedded in the cancellous bone area** (column 17, lines 4-6). The Examiner may have erred in previously referring to FIG. 6 as precisely depicting the artificial hip embedded in the cancellous bone area. Column 17 of St. Ville may indeed relate to determining the parameters for the composite hip replacement, however none of column 17 can remove St. Ville's explicit disclosure of **a finite element model** [that includes] **the artificial hip embedded in the cancellous bone area** (*id.*)

Applicants further argue that:

> It is clear that in this entire passage, only the object to be manufactured is being discussed and that the finite element model only represents the object to be manufactured and not any anatomical feature. The "another layer" referenced by the examiner simply refers to another layer of the composite hip replacement.

The Examiner respectfully traverses this argument as follows.

In contrast to Applicants' conclusion, St. Ville describes a "cortical layer" of the normal bone geometry (column 16, lines 44-46), a "cancellous layer" of the normal bone geometry (*id.*), and "**another layer, namely, the artificial hip embedded in the cancellous bone area**" (column 17, lines 4-6).

Applicants further argue that:

> All of the components illustrated in Figure 6 are components of the object to be manufactured. St. Ville fails to teach or suggest a mesh generator that generates a finite element model or mesh based on both of said geometric model of said anatomical feature(s) and said geometric model of said medical device.

The Examiner respectfully traverses this argument as follows.

Applicants may be correct that all of the components illustrated in Figure 6 are components of the object to be manufactured. However, in contrast to Applicants' conclusion, St. Ville expressly discloses at least **a finite element model** [that includes] **the artificial hip embedded in the cancellous bone area** (column 17, lines 4-6) which meets the claim language of a finite element model that represents both a geometric model of an anatomic feature and a geometric model of a medical device.

Applicants further argue that:

> Furthermore, St. Ville does not teach or suggest simulating an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device. [...] The input stresses or deformations in St. Ville are not determined by simulating an interaction between the anatomical features and the medical device. Instead, the stresses or deformations are only related to the stresses experienced in an in vivo hip. [...] There is no teaching or suggestion of a stress/strain/deformation analyzer that simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device.

The Examiner respectfully traverses this argument as follows.

St. Ville expressly discloses:

> As noted, the fields defined at step 21 represent one or more fields which **will be applied to the object in its intended use. For example, in the case of a prosthetic hip, the field may be the mechanical forces which will be applied to the prosthetic hip after implant in the human body.** [...] The force distributions and orientations are based on in vivo studies report at, for example, Hodge et al..." (column 8, lines 1-15, emphasis added)

Therefore, contrary to Applicants' arguments, the forces described by St. Ville are expressly disclosed as the forces to which the medical device will be subjected after being implanted in the human body.

The Examiner does not fully understand the alleged distinction regarding the "stresses and deformations" being "only related to the stresses experienced in an in vivo hip." There is no claim limitation excluding the simulation of forces to which the medical device will be subjected after being implanted in the human body (i.e., stresses experienced in an in vivo hip).

Further, St. Ville expressly describes the values {f} and {x}:

> Thus, a manufacturer desiring to manufacture a prosthetic hip which responds to the force indicated in FIG. 5A in the same manner as an in vivo hip would define the force {f} to be the force indicated in FIG. 5A and would define the displacements {x} to be the displacements set forth in the table of FIG. 5B. (column 8, lines 39-44)

St. Ville further discloses:

> At step 24, the finite element software package is programmed to solve for the material property matrix [k] using the relationship {f}=[k]{x}.
> [...]
> Since the field {f} and the potential {x} have been defined at step 21, the material property matrix [k] may be calculated. When {f} is the mechanical force field and {x} is the displacement [k] is the stiffness matrix. [...] The calculation of the matrix [k] at step 24 when the fields and potentials have been defined as described at steps 21 determines the optimum or near-optimum material property matrix for **permitting a manufacturer to manufacture an object having desired responses for a specific application, i.e., for a specific application of forces.** (column 10, lines 32-55, emphasis added)

Therefore, St. Ville takes as ***input*** the forces {f} to which the prosthetic device will be subjected after implant in the human body (i.e. "load data on said anatomical feature(s) and/or medical device" in the claim language). St. Ville takes as ***input*** the desired displacements {x} of the prosthetic device under load. St. Ville employs a finite element software package to **calculate** the material property matrix [k]. According to those results, a prosthesis manufactured

according to the material property matrix [k] will exhibit stress/strain/deformation according to the displacements {x}.

Based upon St. Ville's solution material property matrix [k], the finite element software package ("stress/strain/deformation analyzer") predicts that displacements {x} ("stresses, strains, and deformation") will occur in the device when subjected to forces {f} ("load data on said anatomical feature(s) and/or medical device).

Applicants further argue that:

> Such a distinction is further emphasized with respected to dependent claims 5-7 which recite, respectively, that the medical device is an endovascular prosthesis; the medical device is a stent graft; and the medical device is a cardiovascular stent.

The Examiner respectfully traverses this argument as follows.

None of the claims rejected under 35 U.S.C. § 102 as being anticipated by St. Ville recite that the medical device is an endovascular prosthesis, a stent graft, or a cardiovascular stent.

Applicants present parallel arguments directed to the independent claims 16, 31, 54, 70, and 86. Applicants refer to those arguments in addressing the rejection of dependent claims 4, 5-7, 19, 20-22, 33-35, 57, 58-60, 73, 74-76, and 88-90 under 35 U.S.C. § 103. These arguments have been addressed above.

Applicants' arguments have been fully considered but have been found unpersuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 9, 16-18, 24, 31, 32, 36, 54, 56, 62, 70, 72, 78, 86, 91, 113, 115, 117, 118, and 119 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,594,651 to St. Ville.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, St. Ville discloses a system for analyzing medical devices (abstract; column 16, lines 37-58) comprising:

A geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry ... is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below."* (column 9, lines 31-38)];

A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical features and said geometric model of said medical device [*"A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area."* (column 17, lines 4-6); FIGS. 4A, 4B]; and

A stress/strain/deformation analyzer that receives said finite element model or mesh materials properties of said anatomical features and said medical device, load data on said anatomical features, and/or said medical device, and simulates an interaction between said anatomical features and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*"First, a finite element model of the normal bone geometry (both cortical and cancellous layers) is created."* (column 16, lines 44-46); *"A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area."* (column 17, lines 4-6); *"Since the displacement {x} and forces {*

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville discloses that the geometric model of said anatomical features is an idealized geometric model [*"First, a finite element model of the normal bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals..."* (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 9, 24, 36, 62, 78, and 91, St. Ville discloses that the mesh generator includes three-dimensional finite modeling software [*"Other suitable software packages for generating the finite element model include MSC/NASTRAN [...], ABAQUS [...], and ANSYS [...]."* (column 9, lines 54-59)].

Regarding claims 113, 115, 117, 118, and 119, St. Ville discloses that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [*"mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

2. Claims 1, 16, 31, 54, and 70 are rejected under 35 U.S.C. 102(b) as being anticipated by "Interface Mechanics in Lower-Limb External Prosthetics: A Review of Finite Element Models" by Santosh G. Zachariah and Joen E. Sanders (hereafter referred to as Zachariah).

Regarding claims 1 and 16, Zachariah discloses:

A system for analyzing medical devices [*"This review addresses FE modeling of interface stresses in lower-limb external prosthetics."* (abstract)] comprising:

A geometry generator that receives three-dimensional volumetric data of at least one anatomical feature and generates a geometric model of said anatomical feature(s) [*"To **generate***

the model**, the geometry of the object of interest is first discretized into small regularly-shaped polygonal* finite elements; *the elements altogether make up the **FE **mesh.**" (page 289, right column, second paragraph, emphasis added); *"In the case of a limb-socket model for the below-knee (BK) amputee, **the geometric model** typically extends from the mid-thigh to the distal end of the socket, **incorporating the skeleton and musculature of the residual limb, and the liner (if one is used) and shell of the prosthetic socket.**"* (page 289, right column, third paragraph, emphasis added)]

A mesh generator that receives said geometric model of said anatomical feature(s) and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical feature(s) and said geometric model of said medical device (*id.*); and

A stress/strain/deformation analyzer that receives said finite element model or mesh, material properties of said anatomical feature(s) and said medical device, load data on said anatomical feature(s) and/or said medical device and simulates an interaction between said anatomical feature(s) and said medical device to determine the predicted stresses, strains, and deformations of said medical device [*"Of particular interest to the design of prosthetic sockets are the* **interface stresses *between the residual limb and the socket.***" (page 289, right column, last paragraph, emphasis added); *"Properties, such as **stress behavior under strain**, are then assigned to each element. Finally external forces and **displacements** and internal constraints – collectively called the boundary conditions – are applied at appropriate nodes within the mesh. The solution of the FE model corresponds to the minimization of a potential energy functional of*

all the nodal displacements, simultaneously considering the interaction of every element with its neighbors." (page 289, right column, second paragraph, emphasis added)].

Further regarding claim 31, Zachariah discloses the limitations reiterated from claims 1 and 16, and further discloses an *in vitro* anatomical feature as recited [*"In the case of a limb-socket model for the below-knee (BK) amputee,* ***the geometric model typically extends from the mid-thigh to the distal end of the socket****, incorporating the skeleton and musculature of the residual limb, and the liner (if one is used) and shell of the prosthetic socket."* (page 289, right column, third paragraph, emphasis added)].

Further regarding claims 54 and 70, which recite the methods performed by the systems of claim 1 and 16, Zachariah discloses those systems and similarly the method performed by those systems.

Further regarding claim 86, which recites the method performed by the system of claim 31, Zachariah discloses the system of claim 31 and similarly the method performed by that system.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

3. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound*

scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure." (column 7, lines 8-14)].

St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of St. Ville because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

4. Claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "A Finite Element Treatment of the In-Vivo Loading Conditions of NiTi Vascular Stent and Graft Structures" by F. Whitcher (Whitcher, provided by Applicants via PTO-1449 submitted on 3 February 2005).

St. Ville does not expressly teach that the medical device as an endovascular prosthesis, a stent graft, or a cardiovascular stent.

Whitcher teaches finite element simulation analysis of "vascular support structures (stents and grafts) to provide designers with estimates of their in-vivo structural behavior and fatigue properties" (abstract).

St. Ville and Whitcher are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the analysis of cardiovascular stents and grafts as taught by Whitcher with the modeling system of St. Ville because Whitcher expressly teaches that "there is a high priority to deliver high performance vascular stents to the health care practitioner" (page 607, "Introduction") and Whitcher's method provides "simulation analysis of vascular support structures (stents and grafts), to provide designers with estimates of their in-vivo structural behavior and failure properties" (abstract), thereby providing a solution that makes it easier to design and provide successful vascular stents to the health care practitioner.

Claims 20-22, 33-35, 58-60, 74-76, and 88-90 reiterate the limitations of claims 5-7 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 5-7.

5. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

St. Ville does not expressly disclose that the geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

St. Ville and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of St. Ville because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

6. Claims 10-12, 25-27, 37-39, 63-65, 67, 79-81, 83, 92-94, 96, 112, 114, and 116 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claims 10-11, St. Ville does not expressly disclose that the stress/strain/deformation analyzer is a non-linear finite element modeling software application or that the three-dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

St. Ville and Raboin are analogous art because both are directed to modeling of prosthetic joints.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 25-26, 37-38, 63-64, 79-80, and 92-93 reiterate the limitations of claims 10-11 which have been addressed above. These claims are rejected for rationale similar to that given above for claims 10-11.

Claims 12, 27, 39, 65, 81, and 94 have been interpreted as set forth above and are therefore rejected for rationale similar to that given above for claims 10-11.

Regarding claim 112, St. Ville does not expressly disclose that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool.

Raboin teaches that NIKE3D is a "Nonlinear, three-dimensional, finite-element modeling" tool (page 6 of 13, "NIKE3D for Biomechanics"). Therefore, claim 112 is rejected rationale similar to that given above for claim 11.

Claims 67, 83, 96, 114, and 116 reiterate the limitations of claim 112 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 112.

7. Claims 14-15, 29-30, 41-42, 68-69, 84-85, and 97-98 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 1, 16, 31, 54, 70, and 86 above, and further in view of "GRIZ Finite Element Analysis Results Visualization for Unstructured Grids User Manual" by Douglas E. Speck and Donald J. Dovey (Dovey).

St. Ville does not expressly disclose the use of interactive software as a visualization tool that displays one or more of said stresses, strains, and deformations of said medical device via visual representation.

Dovey teaches that GRIZ is "a general-purpose post-processing application supporting interactive visualization of finite element analysis results on unstructured grids. GRIZ calculates and displays derived variables for a variety of analysis codes. Currently, GRIZ works with the family of Methods Development Group (MDG) analysis codes, including DYNA3D, NIKE3D, and TOPAZ3D." (page 1, "Introduction"). Dovey teaches that GRIZ displays the results of

various parameters (page 21, "Results Command"), including various stress results variables (*ex.* "sx", page 21); strain variables (*ex.* "ex", page 22); and deformation (*ex.* "dispx", page 24).

St. Ville and Dovey are analogous art because both are directed toward finite element analysis.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use GRIZ as taught by Dovey to visualize the results of the modeling system of St. Ville because Dovey expressly teaches that "GRIZ provides flexible control of mesh materials on an individual basis, allowing the user to concentrate analysis and visual focus on important subsets of the mesh. GRIZ incorporates the ability to animate all representations over time," thereby enhancing the analysis capabilities present in the system taught by St. Ville to increase productivity.

Claims 29-30, 41-42, 68-69, 84-85, and 97-98 reiterate the limitations of claims 14-15 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 14-15.

8. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over St. Ville as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles... Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed..."* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate... This result corresponds more*

closely to the fractographic findings [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations..."* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the* in vitro *data were simply evaluated..."* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jason Proctor
Examiner
Art Unit 2123

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